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February 12, 2020

**VIA ECF**

Honorable Freda L. Wolfson, Chief Judge  
United States District Court- District of NJ  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street, Court Room 5E  
Trenton, NJ 08608

**Re: *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation*  
MDL No. 2738**

Dear Judge Wolfson:

I am writing in response to plaintiffs' February 11 letter, which purports to provide the Court with "additional scientific materials that support the PSC's general causation experts' opinions." Like plaintiffs' prior letters, this letter does nothing of the sort.

Plaintiffs first reference IARC's statement from November 2019, indicating that the agency plans to reevaluate talc in the next two-and-a-half years in light of additional studies that have been published since talc was first designated as a 2(b) substance in 2010. The fact that IARC plans to re-review the literature, which was announced almost a year ago, obviously says nothing about what IARC will conclude; nor does it in any way support plaintiffs' experts' opinions. Moreover, plaintiffs fail to note that the first development IARC references is the publication of the three cohort studies, none of which found an association between perineal talc use and ovarian cancer.<sup>1</sup> In other words, contrary to plaintiffs' insinuation, there is no reason to believe from IARC's statement that its evaluation will lead it to change the designation for talc from 2(b) (possibly carcinogenic to humans) to 2(a) (probably carcinogenic to humans). Indeed, plaintiffs' own expert, Dr. Anne McTiernan, conceded at the MDL *Daubert* hearing that she "would be speculating" if she were to suggest that IARC would change its conclusions regarding the carcinogenicity of talc.<sup>2</sup> IARC also notes that there is a possibility of confounding in the epidemiological studies and that a study of rats found no evidence of neoplastic changes from talc exposure, neither of which is mentioned in plaintiffs' letter, and both of which further point away

<sup>1</sup> See Report of the Advisory Group to Recommend Priorities for the IARC Monographs during 2020-2024 ("IARC Report") at 72, [https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities\\_2020-2024.pdf](https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf), (Ex. A to PSC Feb. 11, 2020 Letter).

<sup>2</sup> (7/25/19 Hr'g Tr. 919:2-5.)

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from a causal link.<sup>3</sup> In short, the fact that IARC is set to consider the scientific literature over the next several years says nothing about whether plaintiffs' general causation theories are reliable, and the fact that plaintiffs are bringing this to the Court's attention as supposed support for their theories merely highlights their inability to point to any real support from scientific bodies and regulatory agencies for their theories.

Second, the preliminary recommendations of the Interagency Working Group on Asbestos in Consumer Products ("IWGACP") do not bolster the reliability of Dr. Longo's opinions. The recommendations explicitly note that they address "contentious issues that have not been completely resolved or finalized in the ongoing debate."<sup>4</sup> Further, the recommendations expressly are not those of the agencies the IWGACP's members represent and do not constitute proposed changes to any government regulations.<sup>5</sup> Notably, as plaintiffs point out, their own experts participated in, and may have influenced, the proceedings out of which these proposals arose,<sup>6</sup> and there is no indication that regulators intend to adopt these litigation-influenced proposals. Relevant regulations continue to recognize that there is a lack of evidence suggesting that cleavage fragments are dangerous. *See* 57 Fed. Reg. 24,310, 24,310-11 (June 8, 1992) (OSHA concluding that "substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effect as asbestos"). And although the IWGACP premised its preliminary recommendations on the observation that cleavage fragments are "suspected" of causing biological effects akin to those of asbestos,<sup>7</sup> the actual scientific studies have made no such finding, as defendants demonstrated in their *Daubert* presentation.<sup>8</sup> Illustrating this, the IWGACP essentially adopted findings set forth in a 2011 bulletin by NIOSH, which explicitly takes a "precautionary approach" in deeming cleavage fragments countable for its recommended exposure limit for workers and states that evidence on the carcinogenicity of cleavage fragments is "inconclusive."<sup>9</sup>

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<sup>3</sup> IARC Report at 72.

<sup>4</sup> U.S. FDA, Interagency Working Group on Asbestos in Consumer Products, *Executive Summary: Preliminary Recommendations On Testing Methods For Asbestos In Talc And Consumer Products Containing Talc* ("IWGACP Proposal") at 1 n.1, Jan. 6, 2020.

<sup>5</sup> *Id.*

<sup>6</sup> (PSC Feb. 11, 2020 Letter at 3 ("a few PSC experts participated along with interested persons in the [IWGACP's] all-day meeting").)

<sup>7</sup> IWGACP Proposal at 3.

<sup>8</sup> *See, e.g.,* Mossman, *Assessment of the Pathogenic Potential of Asbestiform vs. Nonasbestiform Particulates (Cleavage Fragments) in In Vitro (Cell or Organ Culture) Models and Bioassays*, 52 Regul. Toxicol. Pharmacol. (abstract) (2008) ("The available studies show that cleavage fragments are less bioreactive and cytotoxic than asbestiform fibers."); Gamble & Gibbs, *An Evaluation of the Risks of Lung Cancer and Mesothelioma From Exposure to Amphibole Cleavage Fragments*, 52 Regul. Toxicol. Pharmacol. (abstract) (2008) ("In sum, the weight of evidence fully supports a conclusion that non-asbestiform amphiboles do not increase the risk of lung cancer or mesothelioma."); Addison & McConnell, *A Review of Carcinogenicity Studies of Asbestos and Non-Asbestos Tremolite and Other Amphiboles*, 52 Regul. Toxicol. Pharmacol. S187, S189-S190 (2008) (explaining that five *in vivo* experimental animal studies did not link non-asbestos tremolite to an increased risk of disease, even after prolonged exposure).

<sup>9</sup> *See* IWGACP Proposal at 4 (citing Nat'l Inst. for Occupational Safety & Health, U.S. Dep't of Health & Human Servs., Current Intelligence Bulletin 62, *Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research* (2011)).

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Third, as to the Steffen article, defendants will not repeat their previous submission to the Court about this article, but merely remind the Court that it is a case series involving 10 plaintiffs that was co-authored by three plaintiffs' experts and paid for by plaintiffs' counsel and that the case series lacks any control group of tissue from unexposed women.

Finally, at the risk of stating the obvious, defendants note that plaintiffs' letter-writing campaign appears to miss the point of *Daubert*, which considers the methodologies used by plaintiffs' experts and the body of work they examined. Thus, plaintiffs' counsel's continuing efforts to try to muster *post hoc* support for their experts' opinions is ultimately irrelevant to the Court's analysis.

Respectfully submitted,

/s/ Susan M. Sharko

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cc: All Counsel of Record (Via ECF)